

### REMARKS

This application has been reviewed in light of the Office Action dated July 22, 2004. Claims 1-20 are pending in the application. Claims 1, 18 and 20 are amended in a manner that Applicants believe overcome the rejections in the Office Action. New claim 21 is added. Support for the amendments and new claim can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. Applicants submit that no new matter or issues are introduced by the amendments and new claim.

In the Office Action, claims 1, 3-5, 14-17 and 20 were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 5,997,504 to Bell (Bell '504). However, it is respectfully submitted that amended independent claim 1, claims 3-5 and 14-17 depending therefrom, and amended independent claim 20 clearly and patentably distinguish over the Bell '504 patent.

Referring to FIGS. 4A, 11 and 12A-12C, the Bell '504 patent discloses an assembly base 120 having a cushion adhesive 122, coupled to a needle assembly 104, such that a needle 16 extends through an open space defined by an aperture rim 131. (col. 12, lines 34-40). Aperture rim 131 does not engage needle 16. In contrast, amended claim 1 of the present application recites “[a] safety shield apparatus comprising: a needle shield having a planar contact surface and a needle bearing in the planar contact surface that slidably engages the needle; and a pad having a first surface mountable to the planar contact surface and a second surface configured for engagement with a body surface.” Amended claim 20 of the present application recites, *inter alia*, “[a] safety shield apparatus comprising ... an extensible needle shield having a distal end attached to a planar contact surface ... the shield including a needle bearing in the planar contact surface that slidably engages the needle; and a pad adapted for spacing between a planar contact surface of a safety needle device and a subject’s skin...”

The Bell '504 patent in no way discloses or suggests structure as recited in amended claims 1 and 20. The Bell '504 patent does not disclose, *inter alia*, a safety shield having a distal end mounted with a planar contact surface and a needle bearing in the planar contact surface that slidably engages the needle, and a pad disposed with the planar contact surface. Rather, the Bell

'504 patent shows a base rim that defines an open space adjacent to the needle; the base rim does not engage the needle.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 3-5 and 14-17 depending therefrom, and amended independent claim 20 are patentable and not obvious over the Bell '504 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 2, 6-7, 9-13 and 18-19 were rejected under 35 U.S.C. § 103(a) over the Bell '504 patent in view of U.S. Patent No. 3,918,446 to Buttaravoli (Buttaravoli '446). However, it is respectfully submitted that amended independent claim 1, claims 2, 6-7 and 9-13 depending therefrom, amended independent claim 18 and claim 19 depending therefrom clearly and patentably distinguish over the Bell '504 patent in any combination with the Buttaravoli '446 patent.

The Bell '504 patent has been discussed. Referring to FIG. 1, the Buttaravoli '446 patent discloses a securement device 10 including a bottom pad 12 and an upper pad 14. (col. 3, lines 34-35). In contrast, amended claim 1 of the present application is recited above. Amended claim 18 of the present application recites, *inter alia*, “[a] safety shield apparatus comprising...an extensible needle shield having a distal end attached to a planar contact surface ... the shield including a needle bearing in the planar contact surface that slidably engages the needle; and a pad adapted for spacing between said planar contact surface and a subject's skin...”

The Buttaravoli '446 patent in no way discloses or suggests structure as recited in amended claims 1 and 18. The Buttaravoli '446 patent does not cure the deficiencies of the Bell '504 patent in that the Buttaravoli '446 patent does not disclose, *inter alia*, a safety shield having a distal end mounted with a planar contact surface and a needle bearing in the planar contact surface that slidably engages the needle, and a pad disposed with the planar contact surface.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 2, 6-7 and 9-13 depending therefrom, amended independent claim 18 and claim 19

depending therefrom are patentable and not obvious over the Bell '504 patent in any combination with the Buttaravoli '446 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 7 and 8 were rejected under 35 U.S.C. § 103(a) over the Bell '504 patent in view of U.S. Patent No. 3,645,835 to Hodgson (Hodgson '835). However, it is respectfully submitted that amended independent claim 1 and claims 7 and 8 depending therefrom clearly and patentably distinguish over the Bell '504 patent in any combination with the Hodgson '835 patent.

The Bell '504 patent has been discussed. The Hodgson '835 patent discloses a moisture-vapor-permeable pressure-sensitive adhesive. In contrast, amended claim 1 of the present application is recited above. The Hodgson '835 patent in no way discloses or suggests structure as recited in amended claim 1. The Hodgson '835 patent does not cure the deficiencies of the Bell '504 patent in that the Hodgson '835 patent does not disclose, *inter alia*, a safety shield having a distal end mounted with a planar contact surface and a needle bearing in the planar contact surface that slidably engages the needle, and a pad disposed with the planar contact surface.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1 and claims 7 and 8 depending therefrom are patentable and not obvious over the Bell '504 patent in any combination with the Hodgson '835 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claim 1 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Although Applicants disagree with the rejection, in an effort to expedite prosecution, upon notification of allowance of copending U.S. Application No. 10/016,276 and allowable subject matter of the present application, Applicants will file an acceptable terminal disclaimer that complies with 37 CFR 1.321 (c).

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1-21 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fee(s) which may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

Respectfully submitted,

By:



Mark S. Leonardo  
Reg. No. 41,433  
Customer No. 21710  
Attorney for Applicants  
Brown Rudnick Berlack Israels LLP  
One Financial Center  
Boston, MA 02111  
Tel: 617-856-8145  
Fax: 617-856-8201

#8101194 v1